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VERIFICATION OF TRANSLATION

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Title of the Invention: NEEDLELESS PORT AND METHOD OF MANUFACTURING THE SAME

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am the translator of the document attached and I state that the following is a true translation to the best of my knowledge and belief of Japanese Patent Application No. 2002-235170 (Date of Application: 12 August 2002).

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[TITLE OF THE INVENTION]

NEEDLELESS PORT

[CLAIMS]

[Claim 1] A needleless port comprising:

a septum that is provided with an oval plate at a bottom and a plate having an arbitrary shape on a top face, and includes an intermediate portion between the bottom and the top face having a cross section that has a dimension in a length direction larger than that in a breadth direction,

the septum including a slit having a predetermined depth in a direction orthogonal to the length direction of the cross section, and a bore as an extended continuum of the slit that has an oval shape whose major axis extends in a direction orthogonal to the length direction,

the septum including a bore holding rib in a direction orthogonal to the major axis of the bore, and being made of a resilient material;

a cover, in an inner peripheral portion for covering the septum to hold the same, having a cross section that is in a shape of a circle whose diameter is smaller than the dimension in the length direction of the cross section; and

a pedestal that engages with the cover to hold the septum,

wherein in the intermediate portion of the septum, at least a pair of the bore holding ribs are provided, a thickness portion is provided around the bore, and a thickness stealing portion is provided between the intermediate portion and the cover as an escape place for the septum when the bore is expanded due to insertion of an insertion member, and

when the septum is pushed into the cover, the oval plate and the bore holding rib are compressed by the cover, so that the bore is closed.

[Claim 2] The needleless port according to claim 1, wherein lengths in the major axis and a minor axis of a cross section of the bore gradually become larger from the top face toward the bottom.

[Claim 3] The needleless port according to claim 1 or 2, wherein the septum is formed so as to be substantially level at a central area and to have a protruding thicker portion at an area surrounding the central area.

[Claim 4] The needleless port according to any one of claims 1 to 3, wherein the plate having an arbitrary shape on the top face of the septum is exposed to outside of the cover and is larger in size than an inside diameter of an upper opening of the cover.

[Claim 5] The needleless port according to any one of claims 1 to 4, wherein a surface of the oval plate at the bottom of the septum is flat.

[Claim 6] The needleless port according to any one of claims 1 to 5, wherein a length Ls0 of the intermediate portion of the septum in a state in which the septum is not mounted inside the cover is smaller than a length Lc of the cover at a portion for holding the intermediate portion of the septum therein.

[Claim 7] The needleless port according to any one of claims 1 to 6, wherein with the septum being held inside the cover, an expansion ratio is within a range of 5% to 40%, the expansion ratio being calculated by dividing a length of the septum expanded by holding the septum inside the cover by the length Lc of the intermediate portion of the cover.

[Claim 8] The needleless port according to any one of claims 1 to 7, wherein a ratio of a dimension in the length direction of the oval plate and the intermediate portion to the diameter of the cover is within a range of 1.05 to 1.4.

[Claim 9] The needleless port according to any one of claims 1 to 8, wherein a ratio of a dimension in the breadth direction of the oval plate and the intermediate portion to the diameter of the cover is within a range of 0.8 to 1.

[Claim 10] The needleless port according to any one of claims 1 to 9, wherein an area size of a cross section of the thickness stealing portion in

the intermediate portion of the septum gradually becomes larger from the top face toward the bottom.

[Claim 11] The needleless port according to any one of claims 1 to 10, wherein a ratio of a thickness of the slit to a height of the septum is within a range of 0.04 to 0.60.

[Claim 12] The needleless port according to any one of claims 1 to 11, wherein the thickness of the slit is within a range of 0.2 mm to 3.0 mm.

[Claim 13] The needleless port according to any one of claims 1 to 12, wherein at least two protrusions of the pedestal are fitted into at least two incisions of the cover, and an annular rib of the pedestal engages with a bottom surface of the oval plate of the septum, thereby establishing liquid-tightness.

[Claim 14] The needleless port according to claim 13, wherein an indent, by which a deformed part of the septum can be caught when the insertion member is rotated as being inserted, is provided at an opening of the cover.

[Claim 15] The needleless port according to any one of claims 1 to 14, wherein a peripheral portion at the upper opening of the cover is chamfered.

[Claim 16] The needleless port according to any one of claims 1 to 15, wherein a material of the septum is at least one of silicon rubber, isoprene rubber, butyl rubber, nitrile rubber and thermoplastic elastomer.

[DETAILED DESCRIPTION OF THE INVENTION]

[0001]

[Technical field to which the invention pertains]

The present invention relates to a versatile needleless port that is provided on a medical apparatus and into which a luer lock as well as a luer can be inserted easily and securely.

[0002]

[Prior Art]

In recent years, in view of preventing infection due to accidental needle stick, dull needles as alternatives for sharp metal needles that have

been used conventionally have come into wide use in combination with a port into which the dull needles can be inserted.

[0003]

A medical apparatus using such a dull needle includes a pair of the dull needle (such as a luer or the like) and a port (hereafter, it will be referred to as a needleless port) into which the dull needle can be inserted. Thus, a luer or the like that is adapted to a specific needleless port is necessary.

[0004]

When only a certain kind of luers can be exclusively used with needleless ports adapted thereto, those luers cannot be inserted into the containers and bags that have other kinds of ports, and do not have very high compatibility. When it is difficult to have a luer syringe alone held securely after insertion, a luer lock syringe can be instead as an alternative. There have been developments of needleless ports that have such a structure into which any types of luer syringes and luer lock syringes that meet the normal ISO standards can be inserted.

[0005]

For example, the United States Patent No. 6,089,541 discloses a port in which a deformable septum is disposed so as to be shiftable inside the main body, and the internal structure of the septum, except for the opening, is a hollow. When an insertion member such as a luer is inserted into the opening of the septum, liquid communication is established.

[0006]

In order to make it possible to insert a luer lock syringe as well, a male screw-thread for screw-fastening is provided in the vicinity of the opening of the main body. This allows both a luer syringe and a luer lock syringe to be locked easily and securely.

[0007]

The United States Patent No. 5,699,821 discloses a port in which a

deformable, oblong, and tube-shaped septum is disposed inside the main body so as to be slidable. When an insertion member such as a luer is inserted into the opening of the septum, liquid communication is established. The oblong, tube-shaped septum has a passageway therethrough, and in the natural state, i.e., before the septum is mounted in the main body of the port, the passageway is open. When the septum is mounted in the main body, the function as a septum is exerted by having the entrance (or the exit) compressed.

[0008]

Similarly, in order to make it possible to insert a luer lock syringe as well, a male screw-thread for screw-fastening is provided in the vicinity of the opening of the main body. This allows both a luer syringe and a luer lock syringe to be locked easily and securely.

[0009]

The United States Patent No. 5,474,544 discloses a port in which a deformable septum is mounted inside the main body so as to be expandable. When an insertion member such as a luer is inserted into the opening of the septum, liquid communication is established and the port is filled with the septum having been deformed, thereby preventing fluid leaks.

[0010]

Also in this case, in order to make it possible to insert a luer lock syringe as well, a male screw-thread for screw-fastening is provided in the vicinity of the opening of the main body. This allows both a luer syringe and a luer lock syringe to be locked easily and securely.

[0011]

The conventional needleless ports mentioned above, however, are likely to have a complicated structure, and it is difficult to eliminate the dead space therein. Since there is a space in which bubbles can remain, it becomes impossible to give a patient a blood transfusion or infusion safely.

[0012]

For example, the deformable septum disclosed in the United States Patent No. 6,089,541, has a hollow internal structure except for the opening, and the hollow acts as a dead space. There is a problem in giving a patient a blood transfusion or infusion that it is difficult to remove the bubbles remaining in this dead space.

[0013]

Further, the deformable, oblong, and tube-shaped septum disclosed in the United States Patent No. 5,699,821 has such a structure in which the passageway provided therein is open before the septum is mounted in the main body of the port and is closed by having the entrance (or the exit) compressed when the septum is mounted in the main body. Since the septum is oblong and tube-shaped and therefore, there is a hollow between the entrance and the exit, which acts as a dead space. There is a problem in giving a patient a blood transfusion or infusion that it is difficult to remove the bubbles remaining in the space.

[0014]

As for the septum disclosed in the United States Patent No. 5,474,544, although the problems as stated above are less likely to occur, when the septum is deformed inside the main body, the septum tends to have a hollow therein, and it is difficult to completely avoid formation of a dead space. Further, there remains a practical problem that it is difficult to balance avoidance of a dead space with easiness of insertion of a luer or the like.

[0015]

Among these difficulties, focusing especially on avoiding formation of a dead space, the United States Patent No. 5,354,275 discloses an injecting unit that is to be used with a septum having a slit or a through hole and makes it possible to completely avoid formation of a dead space by structurally solving the problem of having a hollow when a luer or the like is inserted.

[0016]

[Problem to be solved by the invention]

The injecting unit disclosed in the United States Patent No. 5,354,275, however, may cause the following problems.

[0017]

In the structure disclosed in the United States Patent No. 5,354,275, in which the septum has a through hole, when a pressure is applied to the inside thereof and the septum is pressed upward, since the hole is open in the normal state, the hole on the surface of the septum tends to open up easily. Thus, there is a possibility that airborne bacteria and the like stick to the open hole and that the inside of the septum is contaminated.

[0018]

In the structure disclosed in the United States Patent No. 5,474,544, although the septum has a slit therethrough, no additional compressive force is applied in the direction orthogonal to the slit. In such a structure, since the slit is not compressed, there is a possibility that medicinal fluid or the like remains in the slit. In addition, there remains a problem that it is difficult per se to provide a slit at an accurate position in a septum that has a large thickness.

[0019]

As for the structures disclosed in the United States Patents No. 6,089,541 and No. 5,699,821, the internal structure is a hollow except for the opening. It is difficult to perform a priming process with such a structure, and there is a possibility that remaining air that has not been removed in the priming process may be pushed into the tubes during a process of supplying mixed injections. Also, when injected liquid medicine remains in the structure, it is difficult to measure exactly how much medicine has been injected to a patient. Further, in particular, when blood is in the main tube, there is a possibility that thrombi are caused due to the stagnation inside the hollow area.

[0020]

In order to solve the above-mentioned problems, it is an object of the present invention to provide a versatile needleless port in which formation of a dead space at the bottom and in an intermediate portion of a septum that may cause a residual fluid is prevented, and in which the surface of the septum does not open easily even when a pressure is applied.

[0021]

[Means for solving problem]

In order to achieve the above-mentioned object, a needleless port according to the present invention includes: a septum that is provided with an oval plate at a bottom and a plate having an arbitrary shape on a top face, and includes an intermediate portion between the bottom and the top face having a cross section that has a dimension in a length direction larger than that in a breadth direction, the septum including a slit having a predetermined depth in a direction orthogonal to the length direction of the cross section, and a bore as an extended continuum of the slit that has an oval shape whose major axis extends in a direction orthogonal to the length direction, the septum including a bore holding rib in a direction orthogonal to the major axis of the bore, and being made of a resilient material; a cover, in an inner peripheral portion for covering the septum to hold the same, having a cross section that is in a shape of a circle whose diameter is smaller than the dimension in the length direction of the cross section; and a pedestal that engages with the cover to hold the septum. In the intermediate portion of the septum, at least a pair of the bore holding ribs are provided, a thickness portion is provided around the bore, and a thickness stealing portion is provided between the intermediate portion and the cover as an escape place for the septum when the bore is expanded due to insertion of an insertion member. When the septum is pushed into the cover, the oval plate and the bore holding rib are compressed by the cover, so that the bore is closed.

[0022]

With this configuration, even if the septum is pressed upward by an internal pressure, the top face of the septum does not open, thereby preventing contamination. Further, due to the bore holding rib, it is possible to suppress a residual fluid and stagnation of fluid in the bore of the septum. Also, the insertion member such as a luer can be fixed securely. Since there is no dead space, it is possible to give a blood transfusion or infusion safely, and to achieve high levels of both easiness of insertion of the insertion member such as a luer and liquid-tightness.

[0023]

Preferably, in the needleless port according to the present invention, lengths in the major axis and a minor axis of a cross section of the bore gradually become larger from the top face toward the bottom. Since the area size of a cross section of the bore gradually becomes larger towards the bottom thereof, it is possible finally to put out remaining fluid, if any, from the bottom of the septum.

[0024]

Preferably, in the needleless port according to the present invention, the septum is formed so as to be substantially level at a central area and to have a protruding thicker portion at an area surrounding the central area. It is possible to guide the insertion member such as a luer into the passageway of the septum easily, as well as to disinfect the septum with an alcohol cotton ball.

[0025]

Preferably, in the needleless port according to the present invention, the plate having an arbitrary shape on the top face of the septum is exposed to outside of the cover and is larger in size than an inside diameter of an upper opening of the cover. It is possible to prevent the septum from falling inside the cavity of the cover. Further, after the insertion member is taken out, it is easy to have the septum restored.

[0026]

Preferably, in the needleless port according to the present invention, a surface of the oval plate at the bottom of the septum is flat. The septum has hardly any dead space on the bottom thereof.

[0027]

Preferably, in the needleless port according to the present invention, a length Ls0 of the intermediate portion of the septum in a state in which the septum is not mounted inside the cover is smaller than a length Lc of the cover at a portion for holding the intermediate portion of the septum therein. Since the intermediate portion of the septum expands, it is possible to accelerate the restoration of the upper plate when an internal pressure is applied.

[0028]

Preferably, in the needleless port according to the present invention, with the septum being held inside the cover, an expansion ratio is within a range of 5% to 40%, the expansion ratio being calculated by dividing a length of the septum expanded by holding the septum inside the cover by the length Lc of the intermediate portion of the cover. When the expansion rate is smaller than 5%, the restoration force of the top face of the septum is too weak. When the expansion rate is larger than 40%, as a result of an excessive load applied to the septum, the septum gets degraded, for example, the resilience of the septum is lowered, or in an extreme case, the septum itself tends to be damaged.

[0029]

Preferably, in the needleless port according to the present invention, a ratio of a dimension in the length direction of the oval plate and the intermediate portion to the diameter of the cover is within a range of 1.05 to 1.4, and a ratio of a dimension in the breadth direction of the oval plate and the intermediate portion to the diameter of the cover is within a range of 0.8 to 1. When the septum is pushed into the cover, it is possible to ensure that

a compressive force is applied to the bore.

[0030]

Preferably, in the needleless port according to the present invention, an area size of a cross section of the thickness stealing portion in the intermediate portion of the septum gradually becomes larger from the top face toward the bottom. When the insertion member is inserted, it is possible to prevent the septum itself from being twisted.

[0031]

Preferably, in the needleless port according to the present invention, a ratio of a thickness of the slit to a height of the septum is within a range of 0.04 to 0.60, and the thickness of the slit is within a range of 0.2 mm to 3.0 mm. If the bore is formed as a through hole, when the septum is slightly pressed upward due to an excessive internal pressure, there is a possibility that (the bore on) the top face of the septum opens up. When the ratio of the thickness of the slit to the height of the septum is smaller than 0.04, it is difficult to maintain the quality within a stipulated range. When the ratio is larger than 0.60, it is difficult to insert or to hold the insertion member such as a luer. When the thickness of the slit is smaller than 0.2 mm, the aforementioned effect is not obtained. When the thickness of the slit is larger than 3.0 mm, it is difficult to form the slit and to insert or to hold the insertion as stated above.

[0032]

Preferably, in the needleless port according to the present invention, at least two protrusions of the pedestal are fitted into at least two incisions of the cover, and an annular rib of the pedestal engages with a bottom surface of the oval plate of the septum, thereby establishing liquid-tightness.

[0033]

Preferably, in the needleless port according to the present invention, an indent, by which a deformed part of the septum can be caught when the

insertion member is rotated as being inserted, is provided at an opening of the cover. Even when a luer lock syringe is rotated, since the septum is engaged with the indent, the septum is unlikely to get twisted, and it is possible to secure the passageway.

[0034]

Preferably, in the needleless port according to the present invention, a peripheral portion at the upper opening of the cover is chamfered. Even when insertion members are repeatedly inserted into and taken out from the needleless port, it is possible to prevent a corner of the peripheral portion at the opening of the cover from damaging the septum at a part abutted by the corner, protecting the septum from a tear.

[0035]

Preferably, in the needleless port according to the present invention, a material of the septum is at least one of silicon rubber, isoprene rubber, butyl rubber, nitrile rubber and thermoplastic elastomer.

[0036]

[Mode for carrying out the invention]

The following describes a needleless port according to an embodiment of the present invention, with reference to drawings. FIG. 1(a) is a plan view of the needleless port of the embodiment of the present invention. FIG. 1(b) is a cross sectional view of the needleless port of the embodiment of the present invention along a line A-A. FIG. 2 is a cross sectional side view of the needleless port of the embodiment of the present invention along a line B-B.

[0037]

In FIGs. 1 and 2, reference numeral 1 denotes a septum (septum) main body, 2 denotes a surface of the septum 1, 3 denotes a thicker portion in an upper portion of the septum 1, 4 denotes a slit in the septum 1, 5 denotes a bore in the septum 1, 6 denotes a cover, 7 denotes a pedestal, 8 denotes an annular rib, and 9 denotes a thicker portion in a lower portion of

the septum 1.

[0038]

The shape of the septum 1 is shown in FIGs. 3 to 7. FIG. 3 is a perspective view of the septum 1 in the needleless port of the embodiment of the present invention. FIG. 4(a) is a plan view of the septum 1 in the needleless port of the embodiment of the present invention. FIG. 4(b) is a cross sectional view of the septum 1 in the needleless port of the embodiment of the present invention along a line C-C. FIG. 4(c) is a bottom plan view of the septum 1 in the needleless port of the embodiment of the present invention.

[0039]

FIG. 5 is a cross sectional view of the septum 1 in the needleless port of the embodiment of the present invention along a line D-D. FIG. 6 is a cross sectional view of the septum 1 in the needleless port of the embodiment of the present invention along a line E-E. FIG. 7 is a cross sectional view of the septum 1 in the needleless port of the embodiment of the present invention along a line F-F.

[0040]

As shown in FIG. 3, the septum 1 has an upper plate 11 and a lower plate 12, and a connecting portion therebetween is in the shape of an inverse truncated oval cone that has an oval shape in a cross sectional view. In other words, as shown in FIG. 7, the width of the connecting portion, being measured in the direction orthogonal to the bore 5, gradually becomes smaller, from the upper plate 11 toward the lower plate 12. Bore holding ribs 13 are provided in the direction orthogonal to the bore 5, so that a compressive force can be applied to the bore 5.

[0041]

With this configuration, when an insertion member such as a luer is inserted, the deformed parts of the septum 1 can enter between the connecting portion and the cover 6, allowing the inserting operation to be

made easy. At normal times, compressive forces are constantly applied, via the bore holding ribs 13, to the bore 5 in such a direction as to close it. Accordingly, it is possible to ensure that the septum 1 has liquid-tightness. Further, it is also possible to solve the problem of a residual fluid concerned in the United States Patent No. 5,474,544. In order to allow compressive forces to act constantly, the oval shape (bottom surface) of the septum or the cross section of an intermediate portion has a dimension in a length direction or a direction of a major axis larger than an inside diameter of the cover 6.

[0042]

The septum 1 in the needleless port of Embodiment 1 of the present invention is mounted in the cover 6, while expanding the intermediate portion. In other words, the length of the intermediate portion of the septum 1 is smaller than the length of the part of the cover 6 used for holding the intermediate portion of the septum 1. With this configuration, the upper plate 11 of the septum 1 pressed upward by applied pressure can be easily restored to the original position. Also, since the upper plate 11 is pulled toward inside, the slit on the surface of the upper plate 11 is easily closed and sealed. In addition, since the surface is depressed smoothly, it is further easier to stick an insertion member into the slit.

[0043]

Generally, as shown in FIG. 6(a), the intermediate portion of the septum 1 has a shape of an inverse truncated cone whose major axis extends in the same direction as the major axis of the bore 5; however, the present invention is not limited to this configuration, and it is acceptable that the main body 11 has a shape as shown in FIG. 6(b). In other words, it is sufficient if the length in the same direction as the major axis of the bore 5 is smaller than the length in the direction orthogonal to the minor axis of the bore 5. With this configuration, even when a thickness stealing portion is provided, a compressive force that is large enough to close the bore 5 will

be applied.

[0044]

As shown in FIG. 5 or FIG. 7, the septum 1 of the needleless port of Embodiment 1 of the present invention has both the slit 4 and the bore 5.

[0045]

In the case where the slit 4 is not provided, and only the bore 5 composes the passageway, when a pressure is applied, the top face of the septum 1 tends to be raised, so that the thrusting force from the cover (around the septum 1) weakens. Therefore, the bore opens up on the top face, and there is a possibility of contamination by the growth of airborne bacteria and the like.

[0046]

Alternatively, in the case where the bore 5 is not provided, and only the slit 4 is provided, it is difficult to insert an insertion member such as a luer, because a reaction force against the insertion becomes large. Further, it may be difficult to hold an inserted insertion member such as a luer. Furthermore, it is difficult to have a flow channel open, and to perform the formation of such a slit per se, including positioning of the slit at the right position.

[0047]

In order to solve the above-mentioned problems, make it easier to insert an insertion member such as a luer in the case where the passageway is provided, and maintain the liquid-tightness in the case where only the slit 4 is provided, the septum 1 has the slit 4 in the upper portion thereof as well as the bore 5 as an extended continuum of the slit 4.

[0048]

In addition, it is preferable that the ratio Ls/Lh between the thickness of the slit 4 and the height of the septum 1 is within the range expressed by the formula (1), where Ls represents the thickness of the slit 4 and Lh represents the height of the septum 1.

[0049]

Formula (1)

$$0.04 \leq Ls/Lh \leq 0.60$$

When Ls/Lh is smaller than 0.04, there is a possibility that the bore is formed as a through hole due to variations in the manufacturing process, for example. Also, when the internal pressure is applied, the septum opens up on the top face portion thereof. On the contrary, when Ls/Lh is larger than 0.60, it is difficult to insert, hold, and form an insertion member such as a luer.

[0050]

Further, it is preferable that the thickness Ls of the slit 4 is within the range expressed by the formula (2).

[0051]

Formula (2)

$$0.2 \text{ mm} \leq Ls \leq 3.0 \text{ mm}$$

When the thickness Ls of the slit 4 is smaller than 0.2 mm, there is a possibility that the top face of the septum 1 opens up when a pressure is applied. When the thickness Ls of the slit 4 is larger than 3.0 mm, it is difficult to form the slit. Further, it is difficult to maintain the passageway because the open area is small.

[0052]

The slit 4 has a cut in the direction orthogonal to the major axis of the septum 1 in a cross sectional view, and the bore 5 is provided as an extended continuum of the slit 4. The bore 5 has, in a cross sectional view, an oval shape whose major axis extends in the direction orthogonal to the major axis of the septum 1 in a cross sectional view. At normal times, the bore 5 is not closed and fluid is allowed to go therethrough.

[0053]

As shown in FIGs. 4(b), 5, and 7, the bore 5 is formed so that in a vertical cross section, the length in the minor axis and the length in the

major axis of the spindle shape gradually become larger from the interface between the bore 5 and the slit 4 toward the bottom of the septum 1. In other words, the bore 5 is formed so that the width of the open area gradually becomes larger toward the upper plate 12 of the septum 1.

[0054]

With these configurations, it is possible to avoid a leakage of a residual fluid when a luer or the like is taken out as well as to avoid stagnation of fluid. More specifically, as mentioned below, since the septum 1 that has an oval shape in a cross sectional view is to be pushed into the cover 6 to be mounted therein while being compressed into the shape of a perfect circle, compressive forces from the cover 6 are constantly applied to the septum 1 as shown with arrows in FIG. 2. Since the compressive forces are applied to the bore 5 evenly, the closing force is stronger in the upper portion of the bore 5 where the area size of the cross section is smaller. Thus, the fluid that tries to remain in the bore 5 is to be sequentially pushed out toward the lower plate 12 of the septum 1. Finally, the fluid is removed from the end of the bore 5 on the lower plate 12 of the septum 1.

[0055]

As shown in FIG. 1(b), the annular rib 8 of the pedestal 7 engages with the bottom of the septum 1. By providing the annular rib 8 with such a configuration, it is possible to prevent the liquid medicine or the like from leaking between the pedestal 7 and the septum 1.

[0056]

The bottom of the septum 1 is flat. With this configuration, there is no dead space inside the port, eliminating the possibility of causing bubbles or the like to remain in a dead space.

[0057]

As shown in FIG. 4(a), the surface of the upper plate 11 of the septum 1 also has a plate shape. The plate shape on the surface of the upper plate 11 is not particularly limited. In other words, it is possible that

the plate shape on the surface of the upper plate 11 has, in a cross sectional view, an oval shape as shown in FIG. 4A, or alternatively a circular shape. However, it is required at the minimum that the surface of the upper plate 11 have an area size that is larger than an area size of an opening 64 of the cover 6, in a cross sectional view, that the surface of the upper plate 11 have the thicker portion 3, and that the surface of the upper plate 11 have a guide for an insertion member such as a luer by depressing the surface 2.

[0058]

If the area size of the plate shape on the surface of the upper plate 11 of the septum 1 is not larger than the area size of the opening of the cover 6, the upper plate 11 falls inside the cover 6 when an insertion member such as a luer is inserted. For this reason, it is required at the minimum that the surface of the upper plate 11 have an area size that is larger than an area size of the opening of the cover 6.

[0059]

Without the thicker portion 3, there is a possibility that the plate on the surface of the upper plate 11 is also drawn into the cover 6 when an insertion member such as a luer is inserted into the slit 4. Thus, the thicker portion 3 makes it possible to prevent the plate on the surface of the upper plate 11 from being drawn into the cover 6.

[0060]

When the surface of the plate is flat, it is difficult to insert a luer or the like into the slit 4 accurately and, in the case where the contained liquid medicine or the like has leaked in a process of taking out an insertion member such as a luer, to clean it off reliably since there is no place for keeping the liquid. To avoid this, by providing a depression on the surface of the plate, it is possible to guide an insertion member such as a luer into the slit 4 along a tilt. Also, in the case of a leakage of a residual fluid on the surface of the plate, it is easy to clean it off since the fluid can be kept in the depression.

[0061]

A material of the septum 1 should have rubbery resilience in general, and preferably has a stiffness of 20 to 60 measured according to the JIS-A. Specific examples of the material are synthetic rubber such as silicon rubber, isoprene rubber, butyl rubber, and nitrile rubber, thermoplastic elastomer, and the like.

[0062]

The important characteristics required for the material are as follows: (1) slipperiness (effective in insertion and anti-abrasion); (2) resilience (effective in restoration); (3) strength (effective in anti-abrasion and durability); and (4) flexibility (effective in insertion). A material that has all of these characteristics in a good balance is silicon rubber with a stiffness of 30 to 40 (high tear strength) according to the JIS-A stiffness standard.

[0063]

FIGs. 8 are a cross sectional view and a plan view, respectively, of the cover 6 in the needleless port of the embodiment of the present invention. FIG. 8(a) is a cross sectional view of the cover 6 along a line G-G. FIG. 8(b) is a plan view of the cover 6.

[0064]

As shown in FIG. 8, the cover 6, in a portion where the septum 1 is to be mounted, is in the shape of a perfect circle. Thus, the septum 1 that has an oval shape in a cross sectional view in the horizontal direction is to be pushed into the cover 6 to be mounted therein while being compressed into the shape of a perfect circle. In other words, when the septum 1 with the cover 6 is attached to the pedestal 7, compressive forces from the cover 6, as shown with the arrows in FIG. 2, constantly are applied to the septum 1. To the bore 5, larger compressive forces in such a direction as to close the bore 5 are applied from the bore holding ribs 13. Due to these compressive forces that are constantly applied to the septum 1, the bore 5 in the septum

1 can securely keep closed and achieve liquid-tightness, until an insertion member such as a luer is inserted there.

[0065]

On the upper portion of the cover 6, a male screw-thread 61 is formed according to the JIS standard, so that the cover 6 can be engaged with a luer lock syringe. An incision 62 is formed so that the cover 6 is to be fixed when a protrusion of the pedestal 7 is fitted into the incision 16.

[0066]

A material of the cover 6 should have appropriate hardness in order to hold the septum 1 and an insertion member. For example, desirable materials are polyacetal, polypropylene, polyethylene, polyamide, polyethylene terephthalate, polybutylene terephthalate, polycarbonate, and the like.

[0067]

FIG. 9 is a cross sectional view of a state in which an insertion member such as a luer is inserted. With reference to FIG. 9, a description will be given of the case where a luer lock syringe is inserted. As the luer lock syringe is being inserted, the septum 1 is pushed downward so as to draw the upper plate 11, and the thicker portion 3 is caught by the rim inside the upper portion of the cover 6. When the insertion member is further pushed in, a thinner portion, which is positioned more inward than the thicker portion 3, is pulled and expanded. The lower plate portion of the septum 1 that has been compressed by the cover 6 then will be pushed out downward at the bottom of the septum 1. Thus, the compressive force by the cover 6 acting on the septum 1 is released, so that the bore 5 opens.

[0068]

When the luer lock is rotated as being inserted, the male screw-thread 61 to be engaged with the luer lock becomes engaged with a female screw-thread 63 in the luer lock, so that the insertion member can be securely fixed to the port.

[0069]

When the insertion member such as a luer is pulled out, the septum 1 is restored to the shape when the cover 6 is attached due to the actions of the thicker portion 9 and the annular rib 8. It this state, at the bottom of the septum 1, the compressive force by the cover 6 acts again on the lower plate of the septum 1, and thereby the bore 5 closes again.

[0070]

When the luer lock is rotated as being inserted, a twisting force may act on the septum 1 excessively so as to cause the septum 1 to be twisted, depending on the properties of the material of the septum 1. As a result, there is a possibility that the passageway is blocked, or the septum 1 cannot be restored to its original shape after the luer lock is taken out. In order to solve such a problem, it is possible to provide, as shown in FIG. 10, indents 14 in the cover 6. When the indents 14 are provided, as the luer lock is inserted, the deformed parts of the septum 1 are caught by the indents 14. Even when the luer lock syringe is rotated afterwards, due to the indents 14, the septum 1 will not be twisted, and it is possible to maintain the passageway.

[0071]

The indents may have such shapes, as shown in FIG. 10(a), as to cause a reaction force in the direction opposite to the direction of rotation like a knife, or shapes, as shown in FIG. 10(b), like gears with a number of indents.

[0072]

As described above, according to the embodiment, it is possible to fix both a luer syringe and a luer lock syringe as an insertion member securely, to give a blood transfusion or infusion safely since there is no dead space, and to achieve high levels of both easiness of insertion of an insertion member such as a luer and liquid-tightness.

[0073]

[Effects of the invention]

As described above, according to needleless port of the present invention, it is possible to fix both a luer syringe and a luer lock syringe as an insertion member securely, to give a blood transfusion or infusion safely since there is no dead space, and to achieve high levels of both easiness of insertion of an insertion member such as a luer and liquid-tightness.

[BRIEF DESCRIPTION OF THE DRAWINGS]

[FIG. 1] FIG. 1(a) is a plan view of a needleless port of an embodiment of the present invention. FIG. 1(b) is a cross sectional view of the needleless port of the embodiment of the present invention.

[FIG. 2] FIG. 2 is a cross sectional side view of the needleless port of the embodiment of the present invention.

[FIG. 3] FIG. 3 is a perspective view of a septum in the needleless port of the embodiment of the present invention.

[FIG. 4] FIG. 4(a) is a plan view of the septum in the needleless port of the embodiment of the present invention. FIG. 4(b) is a cross sectional view of the septum in the needleless port of the embodiment of the present invention. FIG. 4(c) is a bottom plan view of the septum in the needleless port of the embodiment of the present invention.

[FIG. 5] FIG. 5 is a cross sectional view of the septum in the needleless port of the embodiment of the present invention.

[FIG. 6] FIG. 6 is a horizontal cross sectional view of the septum in the needleless port of the embodiment of the present invention.

[FIG. 7] FIG. 5 is a cross sectional view of the septum in the needleless port of the embodiment of the present invention.

[FIG. 8] FIG. 8(a) is a cross sectional view of a cover in the needleless port of the embodiment of the present invention. FIG. 8(b) is a plan view of the cover in the needleless port of the embodiment of the present invention.

[FIG. 9] FIG. 9 is a cross sectional view of the needleless port of the embodiment of the present invention, into which an insertion member is

inserted.

[FIG. 10] FIG. 10 is a plan view of the cover in the needleless port of the embodiment of the present invention.

[Explanation of letters or numerals]

1 septum
2 depression
3 thicker portion
4 slit
5 bore
6 cover
7 pedestal
8 annular rib
9 thicker portion
11 upper plate
12 lower plate
13 bore holding rib
14 indent
61 (male) screw-thread
62 incision
63 (female) screw-thread
64 cover opening

[Name of the Document] ABSTRACT

[Abstract]

[Objective] It is an object of the present invention to provide a versatile needleless port in which formation of a dead space is prevented, and in which the surface of a septum does not open even when a pressure is applied.

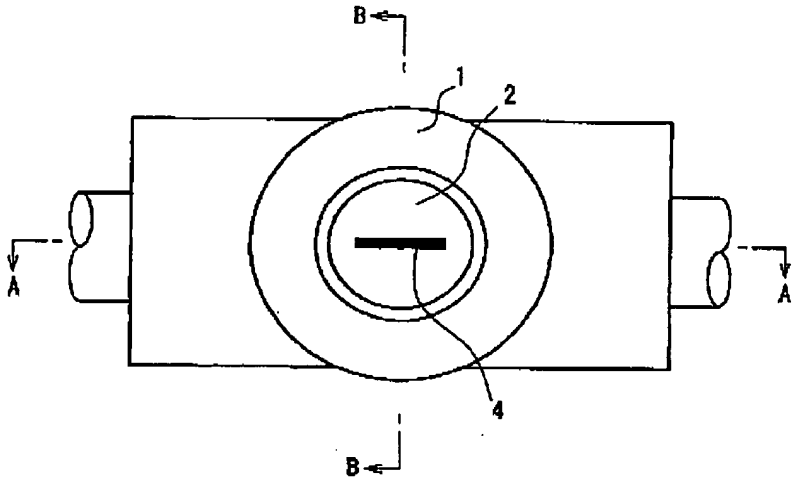
[Means for solving the problem] A needleless port including: a septum that is provided with an oval plate at a bottom and a plate having an arbitrary shape on a top face, the septum including a slit in an intermediate portion in a direction orthogonal to a length direction of an oval cross section, and a bore as an extended continuum of the slit that has an oval shape, the septum including a bore holding rib in a direction orthogonal to a major axis of the bore, and being made of a resilient material; a cover for covering the septum to hold the same having a circular cross section whose diameter is smaller than a dimension in the direction orthogonal to the length direction of the oval cross section and the bore of the bore holding rib; and a pedestal that engages with the cover to hold the septum. At least a pair of the bore holding ribs are provided, a thickness stealing portion is provided between the intermediate portion and the cover as an escape place for the septum, and when the septum is inserted into the cover, the oval plate and the bore holding rib are compressed by the cover, so that the bore is closed.

[Selected Figure] FIG. 1

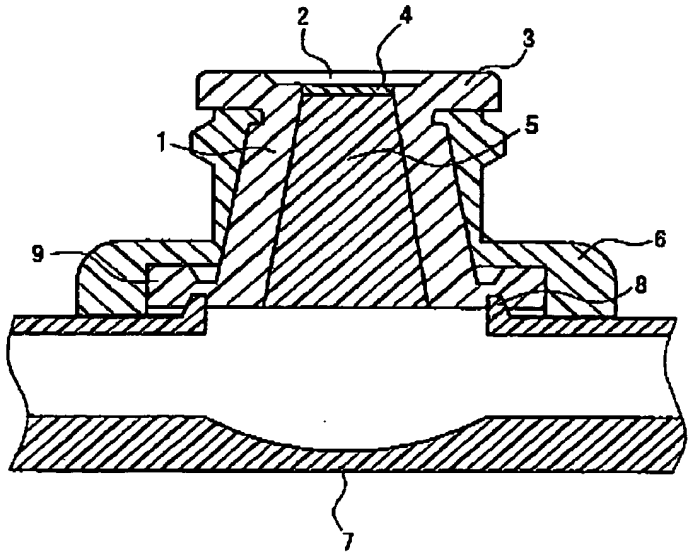
[Document Name] Drawings

[Fig. 1]

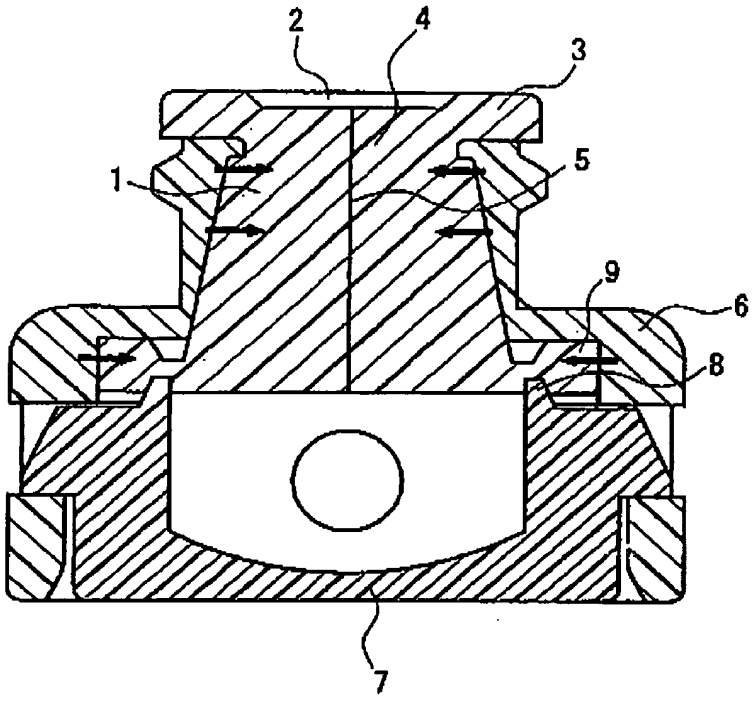
(a)



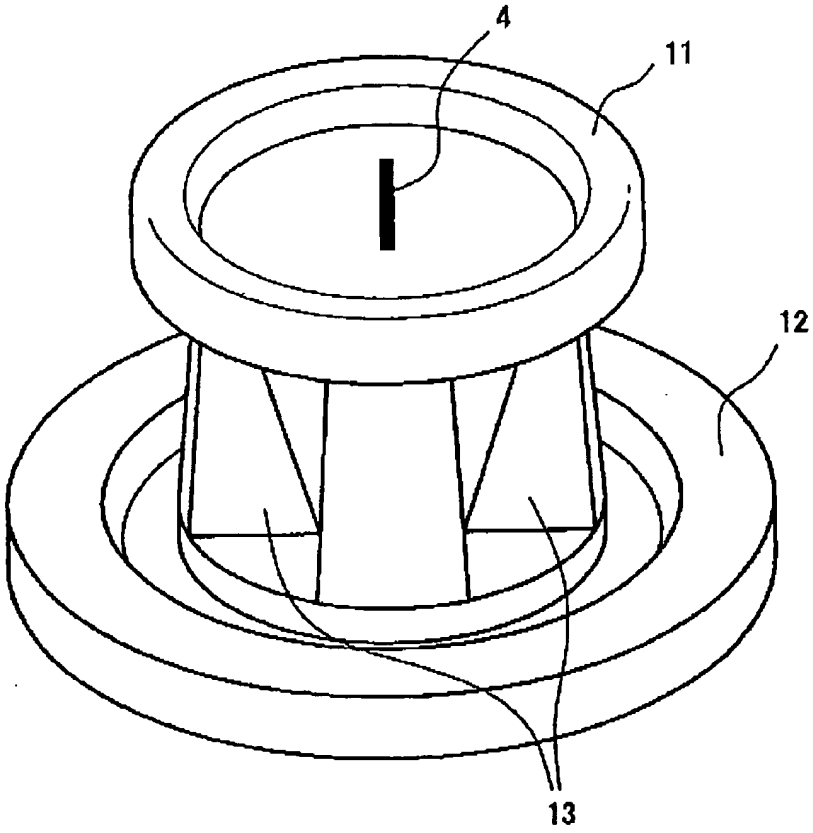
(b)



[Fig. 2]

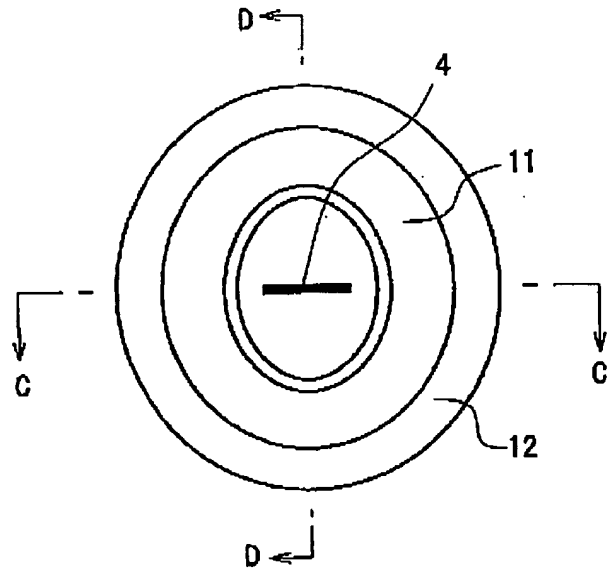


[Fig. 3]

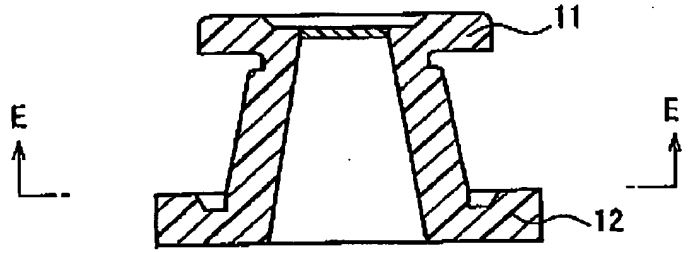


[Fig. 4]

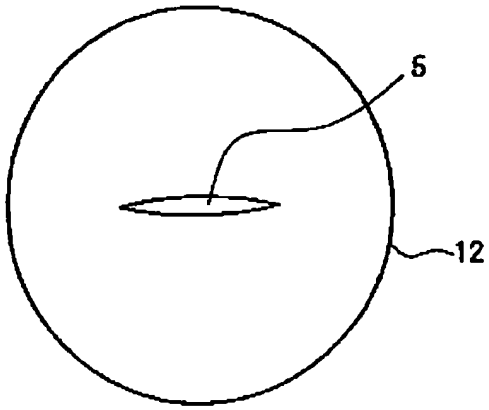
(a)



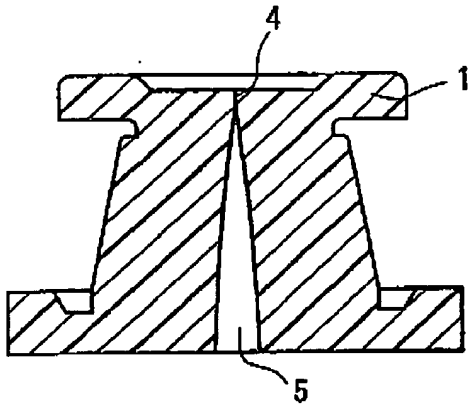
(b)



(c)

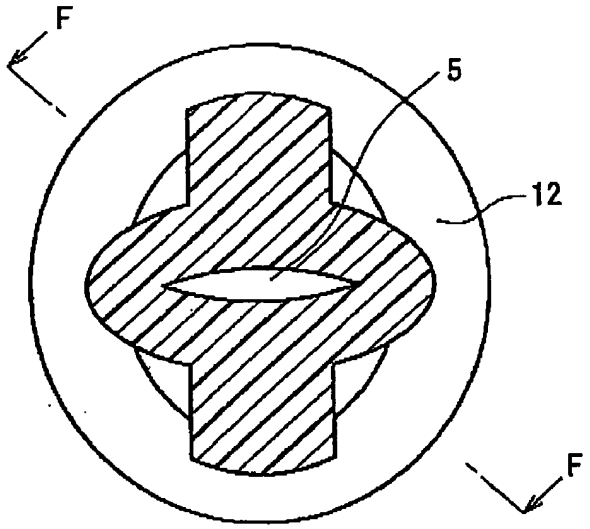


[Fig. 5]

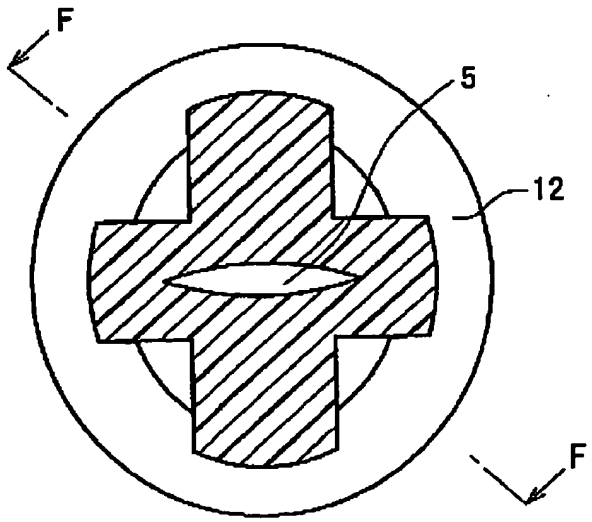


[Fig. 6]

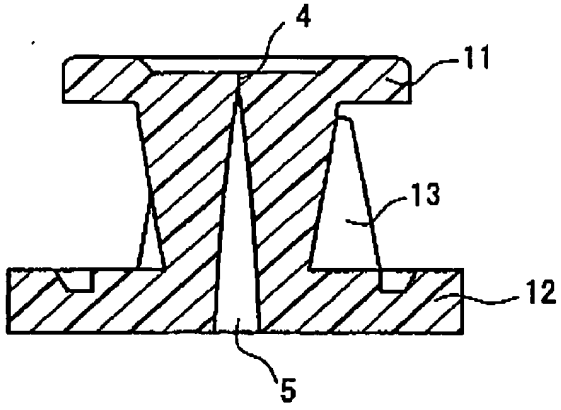
(a)



(b)

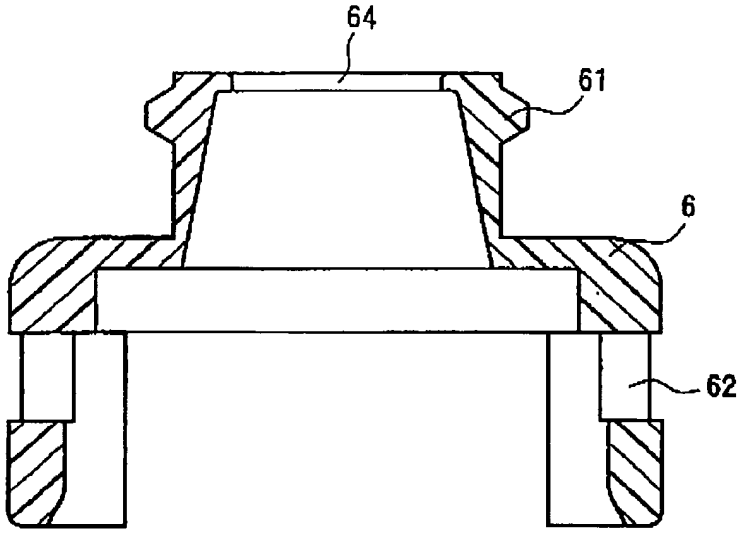


[Fig. 7]



[Fig. 8]

(a)



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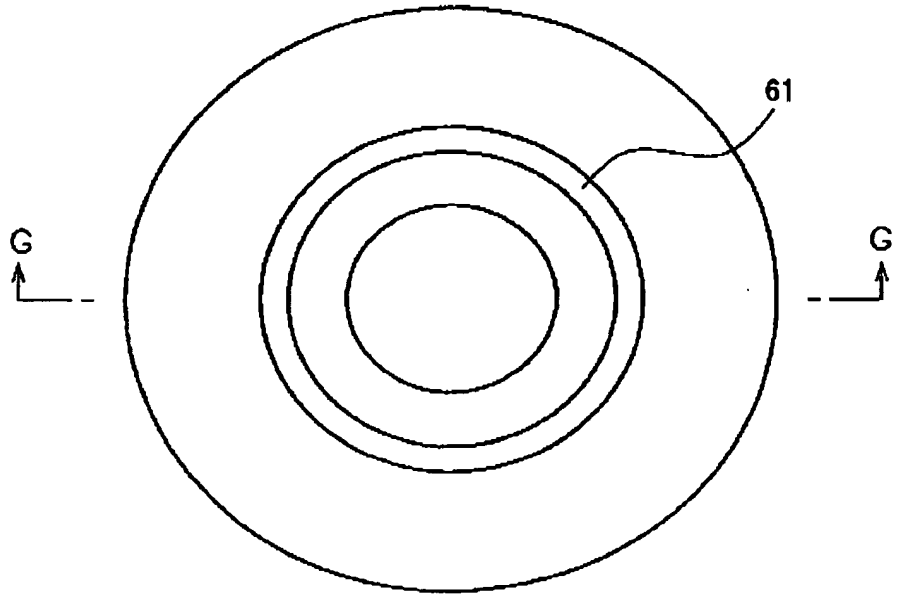
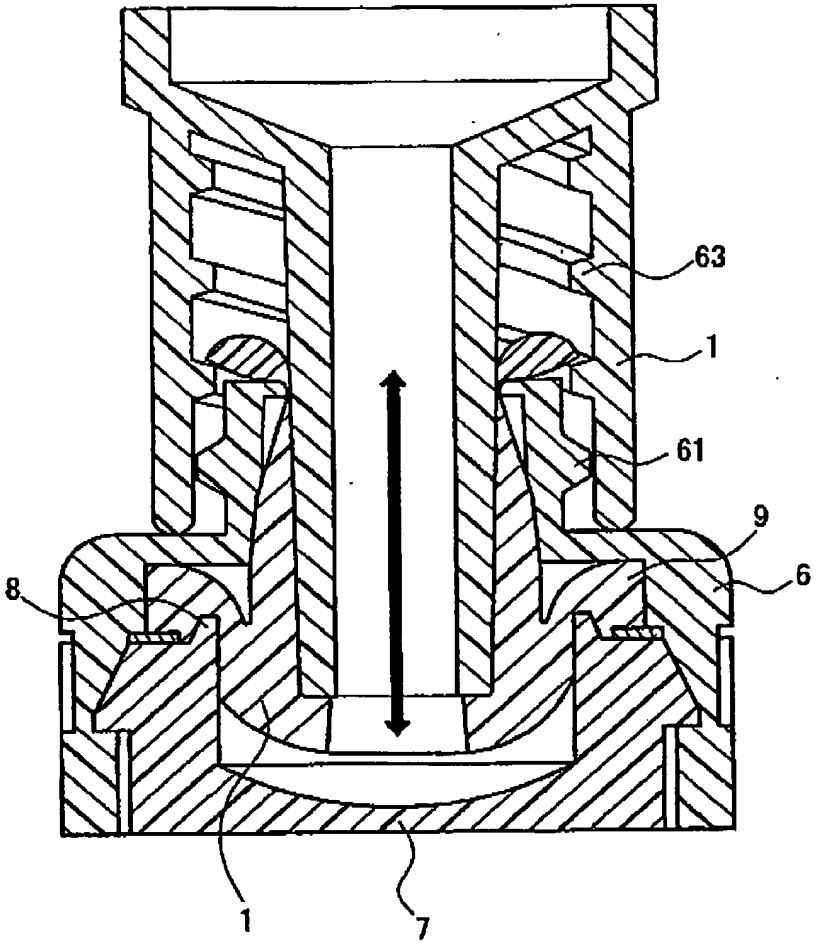
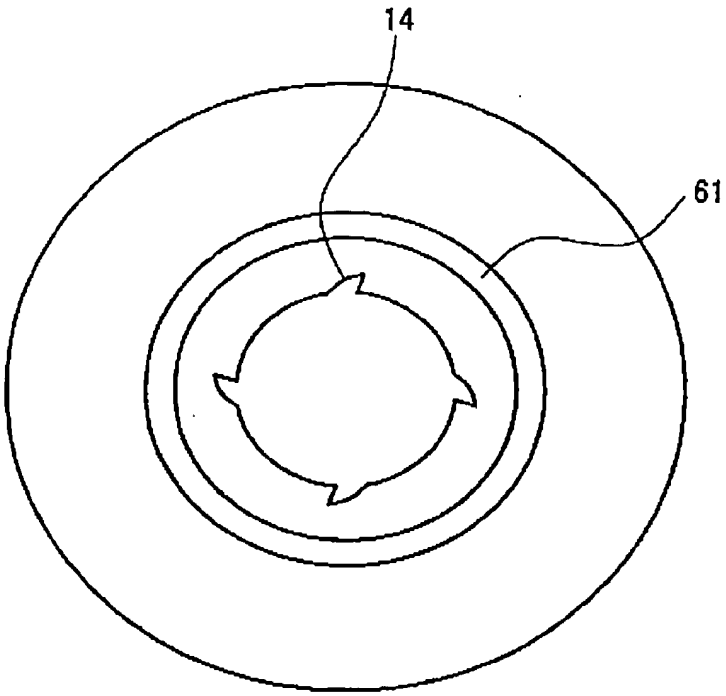


[Fig. 9]



[Fig. 10]

(a)



(b)